

REMARKS

Claims 2, 3, 5, 7-10, 13, 16-17, 20-23, 25-35, 37-40, and 41-45 are pending in the present application. Independent claims 15, 24 and 36 and dependent claims 18-19 are cancelled without prejudice or disclaimer of the subject matter recited therein.

New claims 41-45 are presented. The new claims find support in the specification, claims, and Figures as filed and specifically at page 10 paragraphs 2-3, page 11 paragraph 1, and page 17 lines 16-25. No new matter is added by virtue of the new claims.

Claims 2-3, 5, 7-10, 13, and 15-27 and 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat. 5,399,316) in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522). It is submitted that the resulting combination or modification proffered by the rejection fails to show or suggest a device as recited in claims pending in light of the new claims and accompanying remarks.

As discussed above, claims 15, 18-19, 24, and 36 are cancelled without prejudice or disclaimer of the subject matter recited therein. Regarding independent claims 41, 43 and 45, it is submitted that Yamada fails to disclose or suggest a test element comprising a detection element as recited in the present claims. Specifically, Yamada fails to disclose a detection element having a surface facing the carrier that defines a capillary channel and wherein that detection element includes at least one reagent contained therein.

In that regard, the Examiner's attention is directed to Figure 1 where the reaction region 21 of Yamada is defined by the base member 11, the spacers 12 and 13 and the cover 17. The specification teaches at column 6 lines 55-63 that the specific affinity material is chemically or physically bound to at least one surface of the base member 11, the spacers 12 and 13, or the cover 17. See also, Column 5 lines 54-65. As such, neither the base member 11 nor the cover 17, which face one another, includes at least one reagent contained therein.

Still further, Yamada fails to disclose or suggest a test element comprising a detection element having a surface facing the carrier that defines a capillary channel and wherein the detection element permits liquid penetration therein. In fact, it is submitted that Yamada teaches away from such an arrangement. In that regard, the Examiner's attention is directed to column 7 lines 1-5 of Yamada where it teaches that the sample solution is left held inside the reaction region 21 for a predetermined period of time. Since Yamada teaches the holding of liquid in its reaction region 21, it teaches away from having that liquid penetrate out of that region 21 and into either the base member 11 or the cover 17. As such, neither the base member 11 nor the cover 17 of Yamada is formed to permit liquid penetration therein.

It is submitted that the secondary references when taken either alone or in combination with one another, fail to cure the inadequacies of Yamada. First, Hodges et al. is devoid of description or suggestion of a test element having a detection element formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, as required by each of the independent claims. In that regard, the Examiner's attention is directed to Figures 10 and 11 of Hodges. At most, Hodges teaches that the aperture 8 is defined by opposing palladium coatings 2, 6 and by cylinder side wall 10. As such, Hodges et al. lacks a test element comprising a detection element as recited by the present claims, and fails to cure the inadequacies of Yamada.

Zimmer et al. also is devoid of description or suggestion of a test element having a detection element formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, as required by each of the independent claims. Specifically, Zimmer et al. fails to teach or suggest a channel that is formed at least partially by a first surface of the carrier and a second surface of the detection element, let alone wherein that detection element is formed to permit liquid penetration therein and including at least one reagent contained therein.

The capillary gap 11 of Zimmer in Figures 3 and 4 is simply not defined in part by its areas 6, 7 containing reagent. In that regard, the Examiner's attention is directed to

Figure 3 of Zimmer, where the capillary gap is defined by the fleece 1, covering foil 9, and spacer 10 and Figure 4 where the capillary gap is defined by the fleece 1, support foil 8 and the spacer 10. In each of the Figures 3, 4, the area 6 (Figure 3) and areas 6,7 (Figure 4) fail to form a portion of the capillary gap 11. As such, Zimmer et al. fail to cure the inadequacies of Yamada and Hodges et al.

In light of the above, it is submitted that Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a test element comprising, "a carrier having a first surface, a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, and a capillary channel extending between the first and second surfaces, the channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein a notch is positioned at an edge of the test element forming the sample opening so that a surface opposite to the notch is exposed", as recited in claim 41. Claims 2-3, 5-10, 13, 16-17, 20-23 and 42 depend from claim 41.

It is further submitted that Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a test element comprising, "a carrier having a first surface, and a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element having a second surface facing the first surface and cooperating with the first surface to form at least part of a capillary channel extending between the first and second surfaces, the channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein a notch is positioned at an edge of the test element forming the sample opening so that one side of the edge is discontinuous," as recited by claim 43. Claims 25-35 and 44 depend from claim 43.

Finally, Yamada, Hodges et al., and Zimmer et al. when taken as a whole, fail either alone or in combination to disclose or suggest a method for determining an analyte in

a liquid sample, the method comprising the steps of "providing an analytical test element including a carrier having a first surface, a detection element being formed to permit liquid penetration therein and including at least one reagent contained in the detection element, the detection element including a second surface facing the first surface, and a capillary channel extending between the first and second surfaces, the channel including a sample opening and a vent opening and extends in a direction of capillary transport from the sample opening to at least an edge of the detection element that is nearest to the vent opening, wherein a notch is positioned at an edge of the test element forming the sample opening so that a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the notch so that the liquid sample is transported by capillary forces into the channel, and observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample, wherein the changes relate to a presence of the analyte in the liquid sample". Claims 37-40 depend from claim 36.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments, reconsideration of the rejections of the claims, and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 5 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Pat 5,399,316) in view of in view of Hodges et al. (US Pat. 5,942,102) and Zimmer et al. (US Pat. 5,814,522) as applied to claims 2-3, 7-10, 13, 15-27, and 29-40 above, and further in view of Heller et al. (US Pat. 6,238,624).

Yamada, Hodges et al., and Zimmer et al. have been discussed above with reference to claims 41 and 43. Heller et al. disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. See, the abstract. Heller et al. fail to cure the inadequacies of Yamada, Hodges et al., and

Zimmer et al., in relation to claims 41 and 43. Claim 5 depends from claim 41 and claim 28 depends from claim 43.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

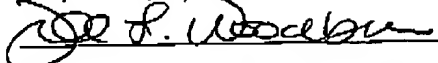
Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815 to Zimmer. The rejection is respectfully traversed. It is respectfully submitted that the two sets of claims do not read on each other. However, if the rejection is maintained, a terminal disclaimer will be submitted upon receipt of a Notice of Allowance for this matter.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that this paper be considered a request for an extension of time and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0044 US).

Date:

2-17-2005

Respectfully submitted,



Jill L. Woodburn, Reg. No. 39,874
The Law Office of Jill L. Woodburn, L.L.C.
128 Shore Drive
Ogden Dunes, IN 46368-1015
Telephone: 219-764-4005/Fax: 219-764-4070